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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/074,782

02/13/2002

Peter DeChant

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03/11/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,782

Applicant(s)

DECHANT ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/2002 as Paper Number 6.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response filed December 10, 2002 as Paper Number 6 to election requirement in Office Action mailed November 08, 2002 as paper number 5 is acknowledged and entered.
2. Claims 1-34 are pending.

Restriction/Election

3. Applicants' election **without** traverse of Group III, Claims 23-34 filed December 10, 2002 as Paper Number 6 to election requirement in Office Action mailed November 08, 2002 as paper number 5 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 1-22 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 23-34 are examined on merits.

Information Disclosure Statement

5. Applicants' Information Disclosure (i.e., IDS) filed May 28, 2002 as paper number 4 has been made of record and considered.

Priority

6. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed does not disclose the claimed spray-dried preparations of either *Bacillus sphaericus* or *Bacillus thuringiensis*, or after the culture slurries of the two organisms have been mixed. Thus, the provisional application does not provide adequate support under 35 U.S.C. §112 for claims 32-34 of this application. Claims 32-34 are assigned the benefit date of 02/13/2002 that is the filing date for instant non-provisional U. S. application number 10/074,782.

Claim Rejections - 35 U.S.C. § 101

7. The following is a quotation of 35 U.S.C. § 101 that form the basis for the rejections under this section made in this Office action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 23-34 are rejected under 35 U.S.C. § 101 as being drawn to nonstatutory subject matter. As written, the claims are drawn to a biological material *per se*, which is a product of nature. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C. §101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Inoculant Co. 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980). The Examiner suggests that applicant use the language "an isolated, biologically pure strain of *Bacillus thuringiensis* and an isolated, biologically pure strain of *Bacillus sphaericus* " in connection with the *Bacillus* spp. to identify a product that is not found in nature.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23-34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a composition comprising two *Bacillus* species.

11. The composition claimed in Claims 23-34 comprising *Bacillus sphaericus* and *Bacillus thuringiensis*, variety (i.e., subspecies) *israelensis* are essential to the invention recited in those claims. The bacterial strains must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism (s) is not so obtainable or available, a deposit of the microorganism (s) in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

In order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number,

showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807 which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit.

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 24-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 24-26 are rendered vague and indefinite by the term "non-genetically modified" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by process since product-by-process claims are intended to define products that are otherwise difficult to define (and/or distinguish from the prior art). Does the term refer to all changes that an occur in the bacterial genome, or only those that are induced by a certain agent (e.g., chemical or physical mutagen) or natural selection or extracting a genomic material from one organism and insertion of the said material via a vector or other means in to a host or in an organism different than from where the material was extracted (e.g., recombinant-DNA technologies). It is important to describe these steps in the claims language because the method of genomic change has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the necessary functional effect(s) instantly claimed and/or disclosed. Since the non-genetic method to obtain the claimed microorganisms comprising the claimed composition is clearly essential to the claimed invention, the steps(s) by which the claimed organisms are obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

16. Claims 23-34 are rejected under 35 U.S.C. § 103 (a) as obvious over Rheume et al. (U. S. Patent 5,560,909) in view of Meadows et al (U.S. Patent 5,501,852).

Claims recite a composition comprising a combination of a strain of *Bacillus sphaericus* and *Bacillus thuringiensis*, subspecies *israelensis* along with a component selected among a surface active ingredient, an inert carrier, a preservative, a humectant, feeding stimulant, attractant, an encapsulating agent, a binder, an emulsifier, a dye, a U.V. protectant, a buffer, a drift control agent, a spray-depositing aid, a free flow agent and a combination thereof", wherein the composition is prepared by spray-drying culture slurries of each of *Bacillus sphaericus* and *Bacillus thuringiensis*, subspecies *israelensis* either separately or post-mixing the slurries of the two bacterial strains.

Rheume et al. disclose "an ingestible bioinsecticidal composition" comprising *Bacillus sphaericus* and/or *Bacillus thuringiensis*, var. *israelensis* along with ultraviolet light stabilizer (Column 14, Lines 43-49; Column 15, Lines 22-31).

Rheume et al. do not disclose spray drying of slurry containing a culture of *Bacillus sphaericus* or *Bacillus thuringiensis* variety *israelensis* or a mixture of culture slurries of said bacteria.

Meadows et al. disclose an entomocidal composition comprising a biologically pure culture of a strain of *Bacillus thuringiensis*, a carrier, a diluent, a surfactant or an application promoting adjuvant (Column 8, Lines 56-60), wherein the concentrated bacterial slurry comprising spore/crystal concentrate is spray-dried into a powder (Column 5, Lines 58-61). Please note that since *Bacillus sphaericus* is a species of Genus *Bacillus*, intrinsically a powdered *Bacillus sphaericus* culture can also be prepared by spray-drying a culture slurry of this bacterium according to Meadows et al's teachings. Please also note that since neither Rheume et al., nor Meadows et al. teach that the said bacterial strains were obtained by either mutation or genetic-recombination of a gene isolated from another organism and

cloned into a *Bacillus* or another appropriate host, intrinsically the said *Bacillus sphaericus* and *Bacillus thuringiensis* variety (i.e., subspecies) *israelensis* strains are genetically unmodified and therefore, Rheume et al. teach an insecticidal composition comprising a spray dried *Bacillus thuringiensis* culture that is genetically not modified and the composition is also comprised of a carrier, a diluent, a surfactant or an application promoting adjuvant.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Rheume et al. according to the teachings from Meadows et al. because both references teach an ingestible bioinsecticide composition comprising genetically unmodified *Bacillus sphaericus* and /or *Bacillus thuringiensis* variety (i.e., subspecies) *israelensis*. Furthermore, while Rheume et al. teach that the composition is additionally comprised of U.V. stabilizer (Column 14, Lines 43-49; Column 15, Lines 22-31), Meadows et al. remedy the deficiency in teachings from Rheume et al. because Meadows et al. teach an insecticidal composition comprising spray dried culture of *Bacillus thuringiensis* with a carrier, a diluent, a surfactant or an application promoting adjuvant (Column 5, Lines 58-61; Column 8, Lines 56-60).

One having ordinary skill in the art would have been motivated to modify teachings from Rheume et al. according to the teachings from Meadows et al. by incorporating genetically unmodified *Bacillus sphaericus* and /or *Bacillus thuringiensis* variety (i.e., subspecies) *israelensis*, ultraviolet light stabilizer, a carrier, a diluent, a surfactant or an application promoting adjuvant and spray dried cultures of *Bacillus thuringiensis* variety (i.e., subspecies) *israelensis* because both references teach an insecticidal composition comprising cultures of *Bacillus sphaericus* and/or *B. thuringiensis* variety (i.e., subspecies) *israelensis* and a carrier material.

None of the prior art references cited above teach the proportions of different components or ratios of *Bacillus thuringiensis* variety (i.e., subspecies) *israelensis* and *Bacillus sphaericus*. However, the adjustment of particular conventional working conditions (e.g., proportions/ratios of different components in a composition, temperature, pH and mode of mixing etc.) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


Conclusion

17. No Claims are allowed.

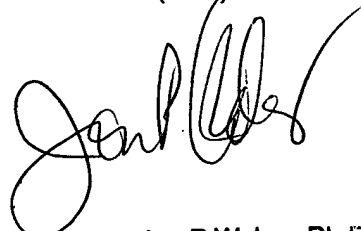
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

March 6, 2003



Jon P. Weber, Ph.D.
Primary Examiner